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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/000,096	12/04/2001	Daiji Naka	2001-1797A	8716

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WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER	
BELYAVSKYI, MICHAIL A	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/000,096	NAKA ET AL.	
	Examiner	Art Unit	
	Michail A Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *23 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *8,11-22,25,29 and 30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 7,9,10,23,24 and 26-28* is/are rejected.

7)☒ Claim(s) *6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 03/23/04 is acknowledged.

Claims 1-30 are pending.

Claims 8, 11-22, 25 and 29-30 stand withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

Claims 1-7, 9-10, 23-24 and 26-28 are under consideration in the instant application.

2. Applicant's Declaration decleares that the hybridoma of an accession number FERM BP-7779 has been deposited under the Budapest Treaty and that said hybridoma will be irrevocably and without restriction or condition released to the public upon the issuance of a patent has obviated the previous rejection of claim 6 under 35 U.S.C. 112 first paragraph.

In view of the amendment, filed 03/23/04 the following rejections remain

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-5 ,7 and 9-10 stand rejected under 35 U.S.C. 102(b) as being anticipated by EP 0596524 (IDS) as is evidenced by Goldsby et al (Immunology, Fifth edition, 2000, pages 137-139) for the same reasons set forth in the previous Office Action, mailed 12/19/03.

Applicant's arguments, filed 03/23/04 have been fully considered, but have not been found convincing.

Applicant asserts that : (i) EP' 524 fails to teach that antibody that recognized an active HGFA does not substantially recognized inactive HGFA ; (ii) the existing monoclonal antibodies directed to HGFA i.e. 7E10, P1-4, A-1, A-6,A-23,A-32, A-51 and A-75) showed reactivities to both active and inactive HGFA.

Contrary to Applicant's assertion, as was stated in the previous Office Action, EP'524 though EP'524 does not explicitly teaches that said antibody does not substantially recognized inactive HGFA, it is noted that antibody taught by EP'524 was obtained against the same antigen, active HGFA, that was made by the same method, as in the instant application i.e. incubation of inactive HGFA with thrombin at 37^0C, resulting in a limited proteolysis of inactive HGFA between argenine at a position of 407 and isoleucine at a position of 408 (see page 10 in particular). Thus the antibody taught by EP'524 would inherently have the same functional properties i.e. does not recognize inactive HGFA , as claimed. Also, it is noted that EP'524 does not teach that antibodies that recognized an active HGFA is one of the 7E10, P1-4, A-1, A-6,A-23,A-32, A-51 or A-75 monoclonal antibodies. Since the office does not have a laboratory to test the reference antibodies, it is applicant's burden to show that the reference antibody does not have the same functional limitations as recited in the claims. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

Claim 2 is included because the claimed functional limitation would be inherent properties of the referenced antibody as is evidenced by by Goldsby et al. Goldsby et al., teach that dissociation constant of antibody used for SDS-PAGE is about $1x\ 10^{-9}$ M(see table 6-1 in particular). In addition, the claimed functional limitation would be inherent properties of the referenced antibody because the referenced antibody was obtained against the same antigen using the same strategy and method as claimed, thus the claimed antibody would inherently shows a dissociation constant of about $1x\ 10^{-9}$ M in the absence of evidence of structural difference.

The reference teaching anticipates the claimed invention.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> *(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.*

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 23-24 and 26-28 stand rejected under 35 U.S.C. 103(a) as being obvious over EP 0596524 in view of Zuk et al. (U.S. Patent No. 4,281,061) for the same reasons set forth in the previous Office Action, mailed 12/19/03.

Applicant's arguments, filed 03/23/04 have been fully considered, but have not been found convincing.

Applicant asserts that because EP'524 does not teach or suggest that the disclosed antibody does not substantially recognized inactive HGFA, the combined references fail to teach each and every element of the claimed invention.

As has been discussed, supra it is the Examiner position that antibody taught by EP'524 does not recognized inactive HGFA, thus the combined references teach each and every element of the claimed invention.

EP '524 does not teach a kit comprising antibody that recognize an active HGFA for detecting or measure active HGFA.

US Patent '061 teaches that reagents of the pharmaceutical compositions can be provided as kits as a matter of convenience , optimization and economy of the users (see col 22, line 62 - col 23, line 4 in particular).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of US Patent '061 to those of EP '524 to obtain a claimed kit comprising antibody that recognize an active HGFA for detecting or measure active HGFA.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because assembling the reagents in a kit format a matter of convenience , optimization and economy of the users as taught by US Patent '061 and the antibody taught by EP '524 can be in a pack or a kit for convenience and economy.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

7. No claim is allowed

8. Claim 6 is objected to as being dependent upon a rejected base claim 1, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/ 272-0840 The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/ 272-0841 .

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michail Belyavskyi, Ph.D.
Patent Examiner
Technology Center 1600
April 19, 2004

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600